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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,918	03/27/2001	Arthur M. Krieg	C1039/7048 (AWS)	4953

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EXAMINER
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ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/818,918

Applicant(s)

KRIEG ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office action is in response to the communications filed 9-15-03.

Claims 1-18 are pending in the instant application.

### ***Election/Restrictions***

This application contains claim 10 drawn to an invention nonelected (SEQ ID NOS. 37,38,40 and 42) with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The declaration under 37 CFR 1.132 filed 9-15-03 is insufficient to overcome the rejection of claims 1-18 based upon a lack of enablement over the broad claimed as set forth in the last Office action for the reasons cited below in addressing Applicants' arguments.

### **Response to Arguments and Amendments**

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action mailed 3-10-03, because the specification, while being enabling for a method of treating an atopic condition in a subject comprising the mucosal or intraperitoneal administration of CpG containing oligonucleotide comprising SEQ ID No: 10 (a.k.a. CpG-ODN 1826), does not reasonably provide enablement for

Art Unit: 1635

the ability to treat an atopic condition in an organism comprising the administration of any CpG containing oligonucleotide.

Applicant's arguments and declaration filed 9-15-03 have been fully considered but they are not persuasive. Applicants have provided examples in both the declaration and accompanying publications (e.g. The Laryngoscope, Vol. 112, pages 1819-1826, October, 2002), as well as in the instant specification that teach the treatment of atopic conditions by various modes of administration of SEQ ID NO: 10 in an appropriate mouse model. Examples of increases in IL-4, IL-6, IL-12 and gamma interferon and a reduction of eosinophils have also been provided following administration, via various modes, of SEQ ID NOS: 7, 8, 10 and 11 either in vitro or in an appropriate mouse model. Applicants argue that atopic conditions encompass a relatively discrete set of disorders and are believed to share a common IgE mediated mechanism or pathogenesis and, according to Applicants, the relatively narrow scope claimed is enabled by the examples provided for the treatment of atopic conditions comprising the administration of any CpG containing oligonucleotide, via any mode of administration. Contrary to Applicants' assertions, the examples provided of the induction of various interleukins in spleen, liver or thymus cells are not representative of the successful treatment of any atopic condition using any CpG containing oligonucleotide. The scope drawn to treating an atopic condition comprising the mucosal or systemic administration of SEQ ID NO: 10 is enabled by the instant disclosure. But this is not necessarily representative of the broader scope, comprising the administration of any CpG containing oligonucleotide. An assumed common mechanism of action does not ensure

enablement for treatment. Effective delivery to appropriate and concentration of a particular CpG containing oligonucleotide necessary for providing treatment effects for a particular CpG containing sequence are still highly unpredictable. SEQ ID No: 10 contains 2 traditional CpG motifs, each of the CpG dinucleotides are flanked 5' by two purines and flanked 3' by two pyrimidines. The success of treating atopic conditions with SEQ ID NO: 10 is not necessarily representative or correlative of the ability to successfully treat any atopic condition with the generic sequences claimed. The in vivo treatment success for these generic sequences require undue experimentation beyond that provided in the instant disclosure. Therefore, the instant scope of enablement rejection is maintained.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1635

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

**JZ**

December 9, 2003